Attorney Reference: 081935/0304772

Page 8

## In the Claims

Please cancel the existing claims without prejudice and insert new claims as follows:

- 1-14. (Cancelled).
- 15. (New) A solid mixed metal compound having phosphate binding capacity and being in a form suitable for oral administration as a medicament, said compound being free from aluminum and containing iron(III) and at least one additional metal M where M is selected from the group comprising magnesium, calcium, lanthanum and cerium, said compound having a phosphate binding capacity of at least 30% by weight of the total weight of phosphate present as measured by any of the following methods (1) or (2), over a pH range of 3 to 7;
  - (1) adding 1 gram of said solid mixed metal compound to 25 ml of 40 mmol l<sup>-1</sup> sodium phosphate buffer solution, homogenizing and gently agitating at room temperature for 30 minutes, centrifuging at 3000 rpm for 5 minutes, filtering through 0.22 µm millipore filter and measuring the soluble phosphate in the supernatant thus produced;
  - (2) adding 1 gram of said solid mixed metal compound to 25 ml of 20 mmol l<sup>-1</sup> sodium phosphate buffer solution, homogenizing and gently agitating at room temperature for 30 minutes, centrifuging at 3000 rpm for 5 minutes, filtering through 0.22 µm millipore filter and measuring the soluble phosphate in the supernatant thus produced.
- 16. (New) A compound as claimed in Claim 15 in which the ratio M:Fe for the precipitated compound is at least 1.1:1.
- 17. (New) A compound as claimed in Claim 15 in which the ratio M:Fe for the precipitated compound is at least 1.3:1.

Attorney Reference: 081935/0304772

Page 9

18. (New) A compound as claimed in Claim 15 in which the ratio M:Fe for the precipitated compound is at least 1.7:1.

- 19. (New) A compound as claimed in Claim 15 in which the ratio M:Fe for the precipitated compound is up to 5:1.
- 20. (New) A compound as claimed in Claim 15 in which the ratio M:Fe for the precipitated compound is up to 2.6:1.
- 21. (New) A compound as claimed in Claim 15 in which the ratio M:Fe for the precipitated compound is up to 2.4:1.
- 22. (New) A compound as claimed in Claim 15 in which the additional metal comprises calcium.
- 23. (New) A compound as claimed in Claim 15 in which the additional metal comprises magnesium.
- 24. (New) A compound as claimed in Claim 15 which contains hydroxyl and/or carbonate ions.
- 25. (New) A compound as claimed in Claim 15 which additionally contains at least one of sulphate, chloride and oxide.
- 26. (New) A compound as claimed in Claim 15, comprising the compound obtained as precipitate from a solution of a mixture of metallic salts.
- 27. (New) A compound as claimed in Claim 15, obtained as the unaged precipitate from said solution of mixed metal salts.
- 28. (New) A compound as claimed in Claim 15, obtained as the washed and unaged precipitate from said solution of mixed metal salts.

Attorney Reference: 081935/0304772

Page 10

- 29. (New) A compound as claimed in Claim 15 having a hydrotalcite type structure.
- 30. (New) A compound as claimed in Claim 15 in which said compound has a phosphate binding capacity of at least 30% by weight of the total weight of phosphate present as measured by method (1) or by method (2) over a pH range of 2 to 8.
- 31. (New) A solid mixed metal compound having phosphate binding capacity and useful as a medicament, said compound being free from aluminum and containing iron(III) and at least one additional metal M, where M is selected from the group comprising magnesium, calcium, lanthanum and cerium, such that the ratio M:Fe is up to 2.6:1, said compound having a phosphate binding capacity of at least 30% by weight of the total weight of phosphate present as measured by any of the following methods (1) or (2), over a pH range of 3 to 7;
  - (1) adding 1 gram of said solid mixed metal compound to 25 ml of 40 mmol l<sup>-1</sup> sodium phosphate buffer solution, homogenizing and gently agitating at room temperature for 30 minutes, centrifuging at 3000 rpm for 5 minutes, filtering through 0.22 μm millipore filter and measuring the soluble phosphate in the supernatant thus produced;
  - (2) adding 1 gram of said solid mixed metal compound to 25 ml of 20 mmol l<sup>-1</sup> sodium phosphate buffer solution, homogenizing and gently agitating at room temperature for 30 minutes, centrifuging at 3000 rpm for 5 minutes, filtering through 0.22 μm millipore filter and measuring the soluble phosphate in the supernatant thus produced.
- 32. (New) A compound as claimed in Claim 31 in which the ratio of M:Fe for the precipitated compound is at least 1.3:1.
- 33. (New) A compound as claimed in Claim 31 having a hydrotalcite type structure.
- 34. (New) A solid mixed metal compound having phosphate binding capacity and useful as a medicament, comprising the compound obtained as an unaged precipitate

Attorney Reference: 081935/0304772

Page 11

from a solution of a mixture of metallic salts, free from aluminum and containing iron(III) and at least one additional metal M, where M is selected from the group comprising magnesium, calcium, lanthanum and cerium, said compound having a phosphate binding capacity of at least 30% by weight of the total weight of phosphate present as measured by any of the following methods (1) or (2), over a pH range of 3 to 7;

- (1) adding 1 gram of said solid mixed metal compound to 25 ml of 40 mmol l<sup>-1</sup> sodium phosphate buffer solution, homogenizing and gently agitating at room temperature for 30 minutes, centrifuging at 3000 rpm for 5 minutes, filtering through 0.22 μm millipore filter and measuring the soluble phosphate in the supernatant thus produced;
- (2) adding 1 gram of said solid mixed metal compound to 25 ml of 20 mmol l<sup>-1</sup> sodium phosphate buffer solution, homogenizing and gently agitating at room temperature for 30 minutes, centrifuging at 3000 rpm for 5 minutes, filtering through 0.22 μm millipore filter and measuring the soluble phosphate in the supernatant thus produced.
- 35. (New) A compound as claimed in Claim 34, comprising the compound obtained as the washed and unaged precipitate from said solution.
- 36. (New) A compound as claimed in Claim 34 having a hydrotalcite type structure.
- 37. (New) A solid mixed metal compound having phosphate binding capacity and useful as a medicament, said compound being free from aluminum and containing iron(III) and at least one additional metal M where M is selected from the group comprising magnesium, calcium, lanthanum and cerium, said compound having a phosphate binding capacity of at least 30% by weight of the total weight of phosphate present as measured by the following method, over a pH range of 2 to 8;

adding 1 gram of said solid mixed metal compound to 25 ml of 40 mmol  $l^{-1}$  sodium phosphate buffer solution, homogenizing and gently agitating at room temperature for 30 minutes, centrifuging at 3000 rpm for 5 minutes, filtering through 0.22  $\mu$ m

Attorney Reference: 081935/0304772

Page 12

millipore filter and measuring the soluble phosphate in the supernatant thus produced;

- 38. (New) A compound as claimed in Claim 15 which further contains carbonate and/or hydroxyl ions, said compound being the unaged precipitate from a solution of a mixture of metallic salts.
- 39. (New) A compound as claimed in Claim 38 in which said compound has a phosphate binding capacity of at least 30% by weight of the total weight of phosphate present as measured by method (1) over a pH range of 2 to 8.
- 40. (New) A solid mixed metal compound having phosphate binding capacity and useful as a medicament, said compound being free from aluminum and containing iron(III) and calcium, said compound having a phosphate binding capacity of at least 30% by weight of the total weight of phosphate present as measured by any of the following methods (1) or (2), over a pH range of 3 to 7;
  - (1) adding 1 gram of said solid mixed metal compound to 25 ml of 40 mmol 1<sup>-1</sup> sodium phosphate buffer solution, homogenizing and gently agitating at room temperature for 30 minutes, centrifuging at 3000 rpm for 5 minutes, filtering through 0.22 μm millipore filter and measuring the soluble phosphate in the supernatant thus produced;
  - (2) adding 1 gram of said solid mixed metal compound to 25 ml of 20 mmol l<sup>-1</sup> sodium phosphate buffer solution, homogenizing and gently agitating at room temperature for 30 minutes, centrifuging at 3000 rpm for 5 minutes, filtering through 0.22 μm millipore filter and measuring the soluble phosphate in the supernatant thus produced.
- 41. (New) A compound as claimed in Claim 15 containing iron(III) and magnesium such that the ratio Mg:Fe is less than 2.9:1.
- 42. (New) A compound as claimed in Claim 15 containing iron(III) and magnesium such that the ratio Mg:Fe is greater than 3.1:1.

Attorney Reference: 081935/0304772

Page 13

- 43. (New) A method for treating hyperphosphataemia, in an animal in need thereof, which comprises administering to said animal, a therapeutically effective amount of a solid, phosphate-binding, mixed metal compound which is free of aluminum and contains iron (III) and an additional metal selected from the group comprising magnesium, calcium, lanthanum and cerium.
- 44. A method as claimed in Claim 43 in which said compound has a phosphate binding capacity of at least 30% by weight, as measured by any of the following methods (1) or (2), over a pH range of 3 to 7.
  - (1) adding 1 gram of said solid mixed metal compound to 25 ml of 40 mmol l<sup>-1</sup> sodium phosphate buffer solution, homogenizing and gently agitating at room temperature for 30 minutes, centrifuging at 3000 rpm for 5 minutes, filtering through 0.22 μm millipore filter and measuring the soluble phosphate in the supernatant thus produced;
  - (2) adding 1 gram of said solid mixed metal compound to 25 ml of 20 mmol l<sup>-1</sup> sodium phosphate buffer solution, homogenizing and gently agitating at room temperature for 30 minutes, centrifuging at 3000 rpm for 5 minutes, filtering through 0.22 μm millipore filter and measuring the soluble phosphate in the supernatant thus produced.
- 45. (New) A method as claimed in Claim 43 containing hydroxyl and/or carbonate ions.
- 46. (New) A method as claimed in Claim 43 in which said compound has a hydrotalcite type structure.
- 47. (New) A method as claimed in Claim 44 in which said compound has a phosphate binding capacity of at least 30% by weight of the total weight of phosphate present as measured by method (1) or by method (2) over a pH range of 2 to 8.

Attorney Reference: <u>081935/0304772</u>

Page 14

48. A method of manufacturing a phosphate-binding medicament suitable for oral administration, said method including the steps of:

producing a solution containing iron(III), at least one additional metal selected from the group comprising magnesium, calcium, lanthanum and cerium, and carbonate and/or hydroxyl ions to produce a solid mixed metal compound which is free from aluminum and contains carbonate and/or hydroxyl ions, iron(III) and said at least one additional metals,

recovering the precipitate; and processing the same to render the same suitable for use by oral administration.

- 49. (New) A method as claimed in Claim 48 in which said solution is maintained at a pH in the pH range from 10.0 to 10.5.
- 50. (New) A method as claimed in Claim 48 in which said solution is produced by combining a first solution containing iron (III) and said additional metal with a second solution containing hydroxyl and/or carbonate ions.
- 51. (New) A method as claimed in Claim 50 in which the rate of combining said first and second solutions is such that the mixed solution has a pH in the range from 10.0 to 10.5.
- 52. (New) A method as claimed in Claim 48 in which the additional metal to iron(III) ratio is in the range from 1:1 to 5:1.
- 53. (New) A method as claimed in Claim 48 in which the precipitate is processed without aging the same.
- 54. (New) A method as claimed in Claim 48 in which the precipitate is filtered and washed prior to processing for oral administration.

Attorney Reference: 081935/0304772

Page 15

- 55. (New) A method as claimed in Claim 54 in which the precipitate as filtered and washed is unaged.
- 56. (New) Use, in the manufacture of a phosphate-binding medicament suitable for oral administration of, a solid mixed metal compound which is free from aluminum and contains carbonate and/or hydroxyl ions, iron(III) and at least one additional metal selected from the group comprising magnesium, calcium, lanthanum and cerium.
- 57. (New) A method for treating hyperphosphataemia, in an animal in need thereof, which comprises administering to said animal, a therapeutically effective amount of a metal sulphate material selected from the group comprising calcium, lanthanum and cerium sulphate, said metal sulphate material having been treated with an alkali solution.
- 58. (New) A metal sulphate material useful as a medicament, selected from the group comprising calcium, lanthanum and cerium sulphate, said metal sulphate material having been treated with an alkali solution and comprising a solid material.
- 59. (New) A material as claimed in Claim 58 in which the alkali is sodium hydroxide.
- 60. (New) A material as claimed in Claim 58 having a phosphate binding capacity of at least 30% by weight of the total weight of phosphate present as measured by any of the following methods (1) or (2), over a pH range of 3 to 7.
  - (1) adding 1 gram of said solid mixed metal compound to 25 ml of 40 mmol l<sup>-1</sup> sodium phosphate buffer solution, homogenizing and gently agitating at room temperature for 30 minutes, centrifuging at 3000 rpm for 5 minutes, filtering through 0.22 μm millipore filter and measuring the soluble phosphate in the supernatant thus produced;
  - (2) adding 1 gram of said solid mixed metal compound to 25 ml of 20 mmol l<sup>-1</sup> sodium phosphate buffer solution, homogenizing and gently agitating at room temperature for 30 minutes, centrifuging at 3000 rpm for 5 minutes, filtering

Attorney Reference: 081935/0304772

Page 16

through  $0.22~\mu m$  millipore filter and measuring the soluble phosphate in the supernatant thus produced.

- 60. (New) A material as claimed in Claim 58 having a phosphate binding capacity of at least 30% by weight of the total weight of phosphate present as measured by method (1) or by method (2) over a pH range of 2 to 8.
- 61. (New) A method of preparing a metal sulphate material, which method comprises treating a solid material comprising at least one sulphate selected from the group comprising calcium, lanthanum and cerium sulphate with an alkali solution.
- 62. (New) A method as claimed in Claim 61 in which the metal sulphate is calcium sulphate.